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K002961
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ZMS Zander Medical Supplies

755 – 8th Court, Suite # 4
P.O. Box 650790
Vero Beach, FL 32965-0790
Tel: 561-569-5955
Fax: 561-569-4430
WATS-Line: 1-800-820-3029
e-mail: sales@zanderIVF.com

510(k) Summary

03 November 2000

Prepared by:

Friedel MW Zander
Zander Medical Supplies, Inc.
755 8th Court, Suite 4
P.O. Box 650790
Vero Beach, FL 32965-0790
(561) 569-5955
(561) 569-4430 fax
fzander@zanderivf.com

Manufactured by:

Minitüb
Abfüll – und Labortechnik GmbH & Co. KG
Hauptstrasse 41
84184 Tiefenbach
Germany
+49 (0) 87 09 92 29 0
+49 (0) 87 09 92 29 39
minitube@minitube.de

Submitted by:

Richard Hampl-Portenlänger
MTG-Germany
Opalstraße 32
D-84032 Altdorf
Germany
+49 (0) 871 935-7900
+49 (0) 871 935-7902 fax
MTG-Germany@T-online.de

Device Names:

Trade Name:	Minitüb Multi-purpose cassettes
Common Name:	Cassettes
Classification:	Accessory, Assisted Reproduction

Class: II **CFR:** 884.6120 **Procode:** 85 MQG

Device Description:

Rectangular or triangular cassettes made of plastic, comprising of two parts; the transparent tubular body and the colored lift. Available in 6 different colors (per size/shape) for better identification of stored samples. The main body is made from PVC, the colored lift for rectangular is made from Plystyrole, and the colored lift for triangular is made of Polyoxymethilen.

Available Sizes:

Item #16980/0601	Rectangular, 15 x 5 x 145 mm, holds 3 French-type straws 0.5cc or 6 French-type straws 0.25cc or 6 Minitübs.
Item #16980/1201	Rectangular, 15 x 5 x 278 mm, holds 6 French-type straws 0.5cc or 12 French-type straws 0.25cc or 12 Minitübs.
Item #16981/0120	Triangular, 18 mm equilateral x 142 mm long, holds 10 French-type straws 0.5cc or 28 French-type straws 0.25cc or 20 Minitübs.
Item #16891/0140	Triangular, 18 mm equilateral x 275 mm long, holds 20 French-type straws 0.5cc or 56 French-type straws 0.25cc or 40 Minitübs.

Indicated Use:

Cassettes can be used for storage of individual or small numbers of straws for cryo-preservation of biological material in liquid nitrogen tanks. They are used as an alternative to goblets (small plastic beakers), which are suitable for storage of bulk quantities only, as in the veterinary industry.

Directions for Use:

To put the straws inside or to take straws out, the lift of the cassette has to be pulled upwards to open the cassette. It is recommended to use tweezers for handling straws in order to maintain the appropriate temperature and to avoid temperature fluctuations.

Hazard Analysis:

Neither the main body nor the lift comes in contact with the patient, gamete or embryo. It is recommended to wear gloves and protective glasses whenever handling in liquid nitrogen or its vapor phase.

Attachments:

Label

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Mr. Fiedel MW Zander
President/CEO
Zander Medical Supplies
755 8th Court, Suite #4
P.O. Box 650790
VERO BEACH FL 32965-0790

Re: K002961
Minitüb Multi-purpose cassettes
Dated: September 19, 2000
Received: September 22, 2000
Regulatory Class: II
21 CFR §884.6120/Procode: 85 MQG

Dear Mr. Zander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002961

Device Name: MTG – Minitüb Multi-Purpose Cassettes

Indications For Use:

Cassettes can be used for storage of individual or small numbers of straws for cryopreservation of biological material in liquid nitrogen tanks. They are used as an alternative to goblets (small plastic beakers), which are suitable for storage of bulk quantities only, as in human reproductive procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-counter Use _____
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002961